DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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MAY 8 2000

WARNING LETTER

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (714) 798-7600

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Joshua G. Carter, Owner
Physical Enhancement
DBA Get Huge
11953 Dorothy Street, Suite #7
Los Angeles, CA 90049

W/L 51-00

Dear Mr. Carter:

This letter is in reference to your firm's marketing and distribution of the product, Tricana (tiratricol). Labeling for this product contains claims, which cause the product to be a drug [section 201 (g) of the Federal Food, Drug, and Cosmetic Act (the Act)].

Objectionable claims for Tricana include the following:

> potent thyroid hormone raises the metabolic rate, dieting, fat burner, and obesity, reducing problematic areas of fat (cellulite).

Tricana is a "new drug" [section 201 (p) of the Act]. Therefore, it may not be legally marketed in this country without an approved New Drug Application [section 505 (a) of the Act].

This drug is also misbranded because its labeling fails to bear adequate directions for the conditions for which it is offered [section 502 (f) (1) of the Act] and its labeling is false and misleading because it suggests that this product is safe and effective for its intended use, when in fact, this has not been established [section 502 (a) of the Act].

In addition, FDA has determined that tiratricol, the active ingredient in Tricana, is not a dietary supplement and further, that this ingredient may represent a serious health risk to users.

This letter is not intended to be an all-inclusive review of all labeling and products your firm may market. In the past you have also distributed the product Triax, a tiratricol product. The above-noted violations also apply to this product. Please be advised that it is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. You indicated in a telephone conversation with our investigator that you are reconsidering your decision not to sell or ship products containing Tiratricol. Failure to promptly correct these violations or the reintroduction of any tiratricol product may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. Your letter should also state what steps you are taking to prevent the reintroduction of any product containing tiratricol. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Please direct any questions you may have to Mark Tucker, Compliance Officer, at the District Office, phone number 949-798-7718. Your written response should be sent to the attention of:

Thomas L. Sawyer
Director, Compliance Branch
Food and Drug Administration
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612

Sincerely,

Mark Roh
Acting District Director

cc: California Department of Health Services, Food & Drug Branch
601 N. 7th Street
Sacramento, CA 94234-7320
Attn: Stuart Richardson, Jr., Chief